

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

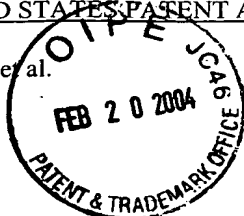
IN RE APPLICATION: Kevin J. TRACEY, et al.

GROUP ART UNIT: 1614

SERIAL NUMBER: 10/619,426

EXAMINER:

FILED: July 16, 2003



FOR: GUANYLHYDRAZONES USEFUL FOR TREATING DISEASES ASSOCIATED WITH T CELL ACTIVATION

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents  
PO BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents were made of record in parent application Serial No. 09/705,581, filed November 2, 2000, now U.S. Patent 6,673,777.

RELATED CASES

- Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- ☐ without fee and within three months of the filing date of the application.
- ☐ without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- ☐ without fee and with the appropriate certification above.
- ☐ without fee and with a new CPA application.
- ☐ without fee and with a Request for Continued Examination.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

PIPER RUDNICK LLP

A handwritten signature in black ink, appearing to read "S. Kelber".

Steven B. Kelber  
Attorney of Record  
Registration No. 30,073

Patrick R. Delaney  
Registration No. 45,338

1200 Nineteenth Street, N.W.  
Washington, DC 20036-2412  
Telephone No. (202) 861-3900  
Facsimile No. (202) 223-2085

**LIST OF RELATED CASES**

<b>Docket Number</b>	<b>Serial or Patent Number</b>	<b>Filing or Issue Date</b>	<b>Status or Patentee</b>
9511-019-27 DIV	6,673,777	November 2, 2000	Patented
9511-020-27	6,143,728	November 7, 2000	Patented
9511-021-27 DIV	5,854,289	December 29, 1998	Patented
9511-022-27 DIV	5,753,684	May 19, 1998	Patented
9511-023-27 DIV	6,008,255	December 28, 1999	Patented
9511-024-27 DIV	5,859,062	January 12, 1999	Patented
9511-026-27 DIV	5,849,794	December 15, 1998	Patented
9511-027-27 DIV	6,248,787	June 19, 2001	Patented
9511-029-27 DIV	6,022,900	February 8, 2000	Patented
9511-030-27 DIV	6,180,676	January 30, 2001	Patented
9511-037-27 CIP	5,750,573	May 12, 1998	Patented
9511-032-27 CIP	5,599,984	February 4, 1997	Patented
*9511-104-27 CONT	10/619,426	July 16, 2003	Pending

The cases listed on this Notice of Related Cases include cases which may contain information that is material to patentability. The listing of a case on this Notice should not be taken as an indication or admission that any information contained therein is material. Prior art for each case listed on this Notice may have been cited. **The files corresponding to the listed cases, which are available to the Examiner, may not have not been examined to ascertain the materiality of any prior art therein.** Accordingly, the Examiner is requested to review the file for each case listed on this Notice in order to assess the materiality of such prior art.

\*Present application; listed for information.

Form PTO 1449 · U.S. DEPARTMENT OF  
(Modified) COMMERCE  
PATENT AND TRADEMARK  
OFFICE



DOCKET NO.

9511-104-27 CONT

SERIAL NO.

10/619,426

APPLICANT

Kevin J. TRACEY, et al.

LIST OF REFERENCES CITED BY APPLICANT  
(Use Several Sheets if Necessary)

FILING DATE

July 16, 2003

GROUP ART UNIT

1614

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	6,008,255	12/28/99	Bianchi, et al.			
	AB	5,859,062	1/12/99	Bianchi, et al.			
	AC	5,849,794	12/15/98	Bianchi, et al.			
	AD	6,022,900	2/8/00	Bianchi, et al.			
	AE	6,180,676	1/30/01	Bianchi, et al.			
	AF	5,750,573	5/12/98	Bianchi, et al.			
	AG	5,599,984	2/4/97	Bianchi, et al.			
	AH	5,753,446	5/19/98	Johnson			
	AI	5,854,289	12/29/98	Bianchi, et al.			
	AJ	5,753,684	05/19/98	Bianchi, et al.			
	AK	6,248,787	6/19/01	Bianchi, et al.			
	AL	6,143,728	11/7/00	Tracey, et al.			

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	BA	Barré-Sinoussi, F., et al., "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)", Science, Volume 220, pp. 868-870 (1983).
	BB	Gallo, R.C., et al., "Frequent Detection and Isolation of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and at Risk for AIDS", Volume 224, pp. 500-503 (1984).
	BC	Teich, N., et al., "RNA Tumor Viruses", Weiss, et al., eds., Cold Spring Harbor Laboratory, pp. 949-956 (1984).
	BD	Mitsuya, H., et al., "Molecular Targets for AIDS Therapy", Science, Volume 249, pp. 1533-1544 (1990). (cited as "1991" in specification)
	BE	Larder, B.A., et al., "HIV with Reduced Sensitivity to Zidovudine (AZT) Isolated During Prolonged Therapy", Science, Volume 243, pp. 1731-1734 (1989). (cited in specification as "Lander et al.")
	BF	Erickson, J., et al., "Design, Activity, and 2.8 Å Crystal Structure of a C <sub>2</sub> Symmetric Inhibitor Complexed to HIV-1 Protease", Science, Volume 249, pp. 527-533 (1990).
	BG	Marshall, C.J., et al., "Specificity of Receptor Tyrosine Kinase Signaling: Transient Versus Sustained Extracellular Signal-Regulated Kinase Activation", Cell, Volume 80, pp. 179-185 (1995).

EXAMINER

DATE CONSIDERED-

\*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		DOCKET NO. 9511-104-27 CONT		SERIAL NO. 10/619,426	
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)				APPLICANT Kevin J. TRACEY, et al.			
				FILING DATE July 16, 2003		GROUP ART UNIT 1614	
				U.S. PATENT DOCUMENTS			
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		6,673,777	01/06/04	TRACEY, et al.			
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BI	Galcheva-Gargova, Z., et al., "An Osmosensing Signal Transduction Pathway in Mammalian Cells", Science, Volume 265, pp. 806-808 (1994).					
	BJ	Kyriakis, J.M., et al., "The Stress-Activated Protein Kinase Subfamily of c-Jun Kinases", Nature, Volume 369, pp. 156-160 (1994).					
	BK	Raingeaud, J., et al., "Pro-Inflammatory Cytokines and Environmental Stress Cause p38 Mitogen-Activated Protein Kinase Activation by Dual Phosphorylation on Tyrosine and Threonine", The Journal of Biological Chemistry, Volume 270, No. 13, pp. 7420-7426 (1995).					
	BL	Han, J., et al., "A MAP Kinase Targeted by Endotoxin and Hypersmolarity in Mammalian Cells", Science, Volume 265, pp. 808-811 (1994).					
	BM	Brewster, J.L., et al., "An Osmosensing Signal Transduction Pathway in Yeast", Science, Volume 259, pp. 1760-1763 (1993).					
	BN	Rouse, J., et al., "A Novel Kinase Cascade Triggered by Stress and Heat Shock that Stimulates MAPKAP Kinase-2 and Phosphorylation of the Small Heat Shock Proteins", Cell, Volume 78, pp. 1027-1037 (1994).					
	BO	Lee, J.C., et al., "A Protein Kinase Involved in the Regulation of Inflammatory Cytokine Biosynthesis", Nature, Volume 372, pp. 739-746 (1994).					
	BP	Sen, J., et al., "Intrathymic Signals in Thymocytes are Mediated by p38 Mitogen-Activated Protein Kinase", The Journal of Immunology, pp. 4535-4538 (1996).					
	BQ	Batchvarova, N., et al., "Inhibition of Adipogenesis by the Stress-Induced Protein CHOP (Gadd153)", The EMBO Journal, Volume 14, No. 19, pp. 4654-4661 (1995).					
	BR	Freshney, N.W., et al., "A Novel Protein Kinase Cascade that Results in the Phosphorylation of Hsp27", Cell, Volume 78, pp. 1039-1049 (1994).					
	BS	Zervos, A.S., et al., "Mxi2, a Mitogen-Activated Protein Kinase that Recognizes and Phosphorylates Max Protein", Proc. Natl. Acad. Sci. USA, Volume 92, pp. 10531-10534 (1995).					
	BT	Geng, Y., et al., "Protein Tyrosine Kinase Activation is Required for Lipopolysaccharide Induction of Cytokines in Human Blood Monocytes", The Journal of Immunology, Volume 151, No. 12, pp. 6692-6700 (1993).					
	BU	Stein et al., Science Vol. 261, pp. 1004-1012, 20 August 1993					
	BV	McLaughlin, M.M., et al., "Identification of Mitogen-Activated Protein (MAP) Kinase-Activated Protein Kinase-3, a Novel Substrate of CSBP p38 MAP Kinase", The Journal of Biological Chemistry, Volume 271, No. 14, pp. 8488-8492 (1996).					
EXAMINER					DATE CONSIDERED		
<p>*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</p>							

Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	DOCKET NO.  9511-104-27 CONT	SERIAL NO.  10/619,426				
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		APPLICANT  Kevin J. TRACEY, et al.					
		FILING DATE  July 16, 2003	GROUP ART UNIT  1614				
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BV	Beyaert, R., et al., "The p38/RK Mitogen-Activated Protein Kinase Pathway Regulates Interleukin-6 Synthesis in Response to Tumour Necrosis Factor", The EMBO Journal, Volume 15, No. 8, pp. 1914-1923 (1996).					
	BW	Shapiro, L., et al., "Specific Inhibition of P38 Mitogen Activated Protein (MAP) Kinase Inhibits <i>in vitro</i> HIV Replication in U1 Cells Induced by Interleukin (IL)-1, Tumor Necrosis Factor (TNF) or Phorbol Esters (PMA)", Eur. Cytokine Network, Volume 7, No. 3, Article No. 375 (1996).					
	BX	Kumar, S., et al., "Activation of the HIV LTR by UV, Cytokines and High Osmolarity Requires CSBP/p38 Activation", Eur. Cytokine Network, Volume 7, No. 3, Article No. 380 (1996).					
	BY	Han, J., et al., "Molecular Cloning of Human p38 MAP Kinase", Biochemica et Biophysica Act, Volume 1265, pp. 224-227 (1995).					
	BZ	Schmidtmayerova, H., et al., "Human Immunodeficiency Virus Type 1 Infection Alters Chemokine $\beta$ Peptide Expression in Human Monocytes: Implications for Recruitment of Leukocytes into Brain and Lymph Nodes", Proc. Natl. Acad. Sci. USA, Volume 93, pp. 700-704 (1996).					
	CA	Raingeaud, J., et al., "Pro-Inflammatory Cytokines and Environmental Stress Cause p38 Mitogen-Activated Protein Kinase Activation by Dual Phosphorylation on Tyrosine and Threonine", The Journal of Biological Chemistry, Volume 270, No. 13, pp. 7420-7426 (1995).					
	CB	Ho, D.D., et al., "Rapid Turnover of Plasma Virions and CD4 Lymphocytes in HIV-1 Infection", Nature, Volume 373, pp. 123-126 (1995).					
EXAMINER					DATE CONSIDERED		
<p>*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</p>							